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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/555,894	11/07/2005	Jordi Tormo i Blasco	4266-0146PUS1	2720	
2292 7599 11/17/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAM	EXAMINER	
			JARRELL, NOBLE E		
			ART UNIT	PAPER NUMBER	
			1624		
			NOTIFICATION DATE	DELIVERY MODE	
			11/17/2008	ELECTRONIC	

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Application No. Applicant(s) 10/555,894 TORMO I BLASCO ET AL Office Action Summary Examiner Art Unit NOBLE JARRELL 1624 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 02 September 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.2 and 5-16 is/are pending in the application. 4a) Of the above claim(s) 6-10 and 12 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1.2 and 5 is/are rejected. 7) Claim(s) 11,13-16 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) information Disclosure Statement(s) (PTO/S6/08)
Paper No(s)/Mail Date \_\_\_\_\_

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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### DETAILED ACTION

### Response to Arguments

- 1. The rejection under 35 U.S.C. 103 has been overcome by the amendment filed 9/2/08.
- The double patenting rejection under obviousness has been overcome by the amendment filed 9/2/08.

#### Claim Objections

3. Claims 14 and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There is no antecedent basis for variable R<sup>4</sup> being a triazole ring in claim 1.

## Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - Determining the scope and contents of the prior art.
  - Ascertaining the differences between the prior art and the claims at issue.
  - Resolving the level of ordinary skill in the pertinent art.
  - Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 1, 2, and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ibrahim et al. (Egyptian Journal of Pharmaceutical Sciences, 1998, 39(1-3), 185-195).

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Determining the scope and contents of the prior art

Ibrahim et al. teach a compound 3 (page 186) in which variable R<sup>4</sup> is a 4,5-dihydro-3-methyl-5-oxo-1*H*-pyrazol-1-yl ring, NR<sup>1</sup>R<sup>2</sup> is NH<sub>2</sub>, variable R<sup>3</sup> is CN (nitrile or cyano), variable L is H, and subscript n is 5. This compound can be used in a variety of ways, including as an anticancer agent, an analgesic, or a bactericide (page 185).

Ascertaining the differences between the prior art and the claims at issue

In the structure reported by Ibrahim et al., variable R³ is attached to the 5-position of the pyrimidine ring and the phenyl ring with substituent L is connected is attached to the 4-position of the pyrimidine ring. In the instant application, variable R³ is attached to the 4-position of the pyrimidine ring and the phenyl ring with substituent L is connected is attached to the 5-position of the pyrimidine ring.

Resolving the level of ordinary skill in the pertinent art

One of ordinary skill in the art can control substitution on different points of attachment on a pyrimidine ring.

Considering objective evidence present in the application indicating obviousness or nonobviousness

In re Norris (84 USPQ 458) teaches that: "Novel and useful compound, which is isomeric with compounds of prior art is not patentable where new compound is not shown to possess new and unexpected properties."

In re Lohr and Spurlin (137 USPQ 54) teaches that H v. Me is not considered patentable evidence of superior, unexpected results. In this case, an H substituent is considered an analogue of a methyl group because the two groups only differ by CH<sub>2</sub>.

In the instant case, it would be obvious to try the specified prepared by Ibrahim et al. because it is a positional isomer of the formula I of the current set of claims and H v. Me is not considered

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patentable for a compound with this core structure. Applicants must show that the positioning of the phenyl ring and variable R<sup>3</sup> is critical to the invention in order to overcome the rejection and/or that H v. Me does produce a critical difference in activity of the compound.

#### Conclusion

- Claims 11, 13, and 15 appear free of the prior art of record.
- Claims 11, 13 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 9. The following is a statement of reasons for the indication of allowable subject matter: Ibrahim et al. (same reference as 103(a)) teach the closest prior art of record. In this compound, variable R<sup>4</sup> is a 4,5-dihydro-3-methyl-5-oxo-1*H*-pyrazol-1-yl ring, NR<sup>1</sup>R<sup>2</sup> is NH<sub>2</sub>, variable R<sup>3</sup> is CN (nitrile or cyano), variable L is H, and subscript n is 5. This compound fails to anticipate or render obvious compounds of claims 13 and 15 because a 4,5-dihydro-3-methyl-5-oxo-1*H*-pyrazol-1-yl ring is not equivalent to a 1-methyl-1H-pyrazol-3(2H)-one ring because the double bond is in a different location in the ring. Ibrahim et al. do not teach pharmaceutical compositions comprising compound 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/ Examiner, Art Unit 1624 /James O. Wilson/ Supervisory Patent Examiner, Art Unit 1624